

**OPTN/UNOS Ethics Committee  
Meeting Minutes  
March 21, 2019  
Conference Call**

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**Introduction**

The Ethics Committee (the Committee) met via teleconference on 03/21/2019 to discuss the following agenda items:

1. Multi-Organ Transplant Paper (MOT) Update

The following is a summary of the Committee's discussions.

**1. Multi-Organ Transplant Paper (MOT) Update**

A UNOS staff member gave an overview of the White Paper, followed by discussion by the Committee.

Data summary:

Every single region has had a majority of sentiment feedback indicating some level of support. All but the Liver Committee expressed support or neutrality for the White Paper.

Themes from Public Comment:

Questions: What about pediatric populations? Why is that not the focus of the paper? There were multiple comments expressing concern about the simultaneous kidney-pancreas (KP) impact.

- One comment felt that worse KDPI kidneys should go to older patients who have less longevity than pediatric patients
- The American Society of Transplantation (AST) comment supported the paper overall, but said, "a significant limitation is the omission of a dedicated discussion on the needs and potential impact on pediatric candidates"

The Committee's Explanations:

- There was some concern from the Committee that focusing on ethical implications for both adult and pediatric populations would prove too complex.
- However, the Committee did modify the paper to incorporate more pediatric analysis based on feedback from the Pediatric Committee

Questions: Why is KP not included as a focus of the MOT paper? It's a common transplant. Also, it impacts pediatrics

- The paper treats KP as single organ transplant from an ethical point of view
- It is less common to implant pancreas without a kidney because both are required to treat single disease process (Type 1 diabetes)
- Both kidney and pancreas are both based on waiting time, unlike other MOT combinations which have one on waiting time (kidney) and one on medical urgency (e.g. heart)
- KP candidates need to meet kidney waitlist criteria

- Additionally, the pancreas may not be utilized if not used in a KP transplant (unlike other MOT)

However...

- The Committee recognizes concern from pediatric standpoint because some low KDPI kidneys go to KP before pediatric kidney

Options

- Identify how KP, while generally treated as a single organ from an ethical perspective, is an MOT combination that can impact SOT in certain situations (i.e. pediatrics)
- The Committee could expand “protected Subgroups” section to further discuss pediatrics and the potential impact of KP and MOT more generally
- The Committee could state that this issue will be addressed separately in future pediatrics MOT
- The Committee could create a plan to work with Pediatrics Committee on a separate ethics paper
- The Committee could clarify why KP was not included in MOT since that generated some confusion in public comment

How do the changes with geography (removing DSA/region) impact the discussion of MOT? Specifically, does removal of DSA disadvantage MOT candidates?

- The paper does not explicitly discuss geography changes and how that impacts the ethical dilemmas with MOT
- However, as long as there are “local” geographic criteria, the MOT candidates may get prioritized out to that circle size. So, SOT candidates could get potentially impacted

Options

- The Committee could acknowledge potential for removing DSA/region on MOT, but avoid being speculative
- The Committee could identify that SOT could be impacted if MOT gets priority out to a wider geographic distribution

Other Comments/Suggestions:

- Treatment options other than transplantation" section should discuss dialysis more as a viable treatment option
- The Committee could consider additional priority point system when kidney disease burden greater than other disease burden to level the playing field
- The Committee could address disadvantaged groups with waiting time threshold: e.g. additional priority for longer WT
- The Committee could include more data on longevity issues with renal transplants and MOT

#### Summary of discussion:

One member expressed the desire to use more data in order to analyze the validity of the concerns of KP stratification among adults as compared to pediatric patients. Another member spoke up in favor and wants to look into including the p-values of the research data requested by the Committee. A UNOS staff member said they would consult with the research department.

One member asked if it was possible to examine data specifically regarding the wait time of pediatric patients in an area with a KP program.

One member stated that based on their experience the need for KP for pediatric patients was extremely rare. A UNOS staff member explained that part of the benefits of KP transplant was based off of life year benefits (LYB) post graft and that research has shown that KP has a very high LYB compared to other transplants.

One committee member commented that the White Paper already addresses the reason that KP is not included in the paper. One member who presented to the Pancreas Committee shared that the Pancreas Committee had some helpful feedback supporting the exclusion of KP from analysis. The member shared that the Pancreas Committee felt that it would be doing a disservice to treat KP like the other MOT combinations due to the unique nature of KP, namely that KP has a much more standardized process than many other combinations, and that both organs in KP are necessary to treat a common disease. The sentiment was that by comparing it to other multi-organ combinations that don't treat a specific disease that it would be a disservice to KP.

One member asked if the Ethics Committee should decide to pursue a White Paper on the subject focused solely on pediatrics. Another member chimed in that the current white paper does make implications of a future paper focused on pediatrics and that such a paper would be the best place to address the pediatric concerns. Another member shared that while it would be a worthy project that it was unwise for the Committee to promise anything, especially since projects are not guaranteed to be approved by the Policy Oversight Committee.

The Committee discussed how to deal with the subject of simultaneous liver-kidney transplants (SLK). One Committee member suggested that the Committee added additional information regarding criteria for SLK and an explanation of the Committee's recommendation of the "safety net" policy for other combination. One member suggested that the Committee add some clarifying language as to how the current White Paper differs from a previous SLK paper. Another Committee member volunteered to draft such a section.

One Committee member felt that the Committee had already addressed the unknowable impact of new geography allocation systems in the White Paper. Many other Committee members agreed and felt it was unnecessary to add more information on this subject.

Multiple members spoke in agreement to create a glossary of ethical terms as suggested by the Patient Affairs Committee. One specifically suggested creating a type of reference glossary that could be used for much of the Committee's work as the same concepts are shared by many. A Committee member suggested this could make a good future project.

One Committee member made note that the Patient Affairs Committee also found the White Paper challenging to read for the lay person. Another Committee member suggested writing "take away" sections so that people would be able to skim the paper for understanding since the paper is 15 pages.

#### Next steps:

The Committee will work with UNOS staff to incorporate the agreed changes to the MOT paper before the Committee votes to send it to the Board.

#### **Upcoming Meetings**

- April 4, 2019 – teleconference
- April 8, 2019 – in person